



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-E-2079]

Determination of Regulatory Review Period for Purposes of Patent Extension;

BRAVECTO; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or Agency) published a notice in the *Federal Register* of February 12, 2018. After review of a timely request for reconsideration by the applicant of the determination of the regulatory review period of the animal drug, BRAVECTO, in that notice, FDA has determined that a revision of the SUPPLEMENTARY INFORMATION section is warranted. This document presents the revised regulatory review period.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

Correction

In the *Federal Register* of February 12, 2018 (83 FR 6033), in FR Doc. 2018-02761, in the first column, the first two paragraphs under the section “II. Determination of Regulatory Review Period,” the following correction is made on page 6034:

FDA has determined that the applicable regulatory review period for BRAVECTO is 1,054 days. Of this time, 1,016 days occurred during the testing phase of the regulatory review period, while 38 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) became effective:* June 28, 2011. The applicant claims February 19, 2010, as the date the investigational new animal drug application (INAD) became effective. However, after consideration of additional information presented by the applicant in response to the *Federal Register* notice (83 FR 6033), FDA has determined that the start of the testing phase was June 28, 2011, which was the date the first major health or environmental effects test began.

Dated: June 3, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-12284 Filed: 6/10/2021 8:45 am; Publication Date: 6/11/2021]